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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/391,053 | 09/07/99 | ROBL | J |

023914
MARLA J MATHIAS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON NJ 08543-4000

HM22/0907

BAHAR, EXAMINER

ART UNIT

PAPER NUMBER

09/07/01 15

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/391,053

Applicant(s)

ROBL ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 25 and 28, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 14-15 in part; 12-13 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-15 in part is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the first office action of March 21, 2001, amendment and remarks submitted June 25, 2001 and supplemental response submitted June 28, 2001 (Paper Nos. 13 and 14 respectively) are acknowledged.

Claims 1-11 and 14-15 are withdrawn from consideration in part, insofar as they are drawn to an invention other than Group I as being drawn to a non elected invention and specie.

Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected specie.

Claims 1-11 and 14-15 are herein examined on the merits in so far as they read on the elected specie.

This application contains claims 12-13, 16-20 and 1-11 (in part) and 14-15 (in part) drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's remarks and amendments regarding the rejection of claim 5 under 35 USC § 112, second paragraph in the prior office action have been considered and are found persuasive to remove the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "hydrogen bond donator or acceptor" in claims 3 and 4 is vague and indefinite in that it is not clearly understood by the Skilled Artisan. It is important to note that Bronsted-Lowry defines acids as proton donors and bases as proton acceptors. Additionally, a Lewis acid is an electron acceptor and a Lewis base is an electron donor. Organic Chemistry, 2nd edition pages 26 and 32. Therefore, describing an aP2 inhibitor a compound as a "hydrogen bond donor or acceptor" is unclear and indefinite as to what exactly is being donated or accepted by the compound.

Applicant's response and supplemental response submitted June 25, 2001 and June 28, 2001 including the March and Bodansky references concerning the definition of a "hydrogen bond" have been considered, but are not persuasive to remove the rejection under 35 USC section 112, 2nd paragraph. Note that "hydrogen bond" is clearly understood by the skilled artisan and applicant's response and supplemental response clarify the definition of "hydrogen bond". However, applicant does not describe the meaning of a "hydrogen bond donator" or a "hydrogen bond acceptor". Is the skilled artisan to interpret "hydrogen bond donator" as a hydrogen (i.e. proton) donor? Is the skilled artisan to interpret "hydrogen bond "acceptor" as a hydrogen (i.e. proton) acceptor? How is the **bond** being donated or accepted? The scope of the claims is indefinite as to the structure of aP2 inhibitor groups encompassed thereby.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 14-15 in part are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotamisligil et al. in view of Failli et al. (USPN 5,218,124) as disclosed in the specification beginning at the top of page 4. This rejection is of record in the prior office action.

Hotamisligil et al. teaches that aP2 deficient mice do not develop diabetes, see abstract.

Hotamisligil et al. does not teach that the elected oxazole compound specie is an aP2 inhibitor.

Failli et al. (USPN 5,218,124) teaches that oxazole derivative compounds including the elected compound herein are known aP2 inhibitors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected oxazole derivative compound herein in a method for the treatment of diabetes.

One of ordinary skill in the art would have been motivated to employ this oxazole compound in a method of treating diabetes since it is a known aP2 inhibitor. Therefore, it would be reasonably expected to be therapeutically useful in the treatment of diabetes similar to any other compound which reduces or antagonizes aP2 activity.

Applicant's remarks that Failli et al. (USPN 5,218,124) teaches that compounds at issue (i.e., oxazole derivatives)^{are} PLA2 inhibitors and not aP2 inhibitors have been considered but are not found persuasive to overcome the rejection. Note that in the first office action, the examiner

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has referred to Failli et al. (USPN 5,218,124) as disclosed in the specification beginning at the top of page 4. The examiner has cited to nothing more than the applicant's admissions regarding the prior art. On page 4 of the specification applicant admits that:

“Examples of aP2 inhibitors suitable for use herein include compounds which include an oxazole or analogous ring. Thus, U.S. Patent No. 5,218,124 to Failli et al. (the disclosure of which is incorporated herein by reference) discloses compounds which have activity as aP2 inhibitors and thus suitable for use herein....”

When applicant states that something is prior art, it is taken as being available as prior art against the claims. Admitted prior art can be used in obviousness rejections. *In re Nomiya*, 184 USPQ 607, 610 (CCPA 1975). *In re Hellsund*, 177 USPQ 170, held that statement made by applicant, whether in patent application or in other papers submitted during prosecution, that certain matter is prior art to him, is an admission that that matter is prior art for all purposes, whether or not a basis in 35 U.S.C. 102 can be found for its use as prior art.

The claimed methods are considered obvious over the cited prior art, absent evidence to the contrary. No such evidence is seen.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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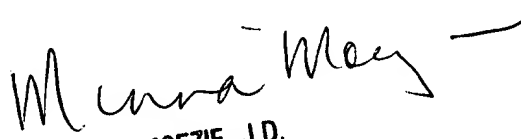
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 29, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600